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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,129	CO ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/5/04; 6/8/04

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 18, 21, 23-27

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 18, 21, 23-27

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 4/5/05, has been entered.
Claims 1-17, 19-20 and 22 have been canceled.
Claim 18 has been amended.
Claims 18, 19 and 21 have been amended.

Applicant's amendment, filed 6/8/04, has been entered.
Claim 18 has been amended

Claims 18, 21 and 23-27 are pending.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's amendments and arguments, filed 4/5/05 and 6/8/04.
The rejections of record can be found in the previous Office Action, mailed 10/3/03.

3. Applicant's amendment of priority on the first line of the specification is acknowledged.
However, applicant is required to indicate the relationship between the priority documents.
See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

4. Given applicant's amendment, filed 6/8/04, which changes the SEQ ID NOS., applicant is invited to review the Abstract to determine if the correct SEQ ID NOS. are indicated.

5. Claims 18, 21 and 23-27 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: the recitation of claim 18(a) and (b) as it reads on the CDRs and framework regions of generic humanized immunoglobulins employed in the claimed methods of treating thrombotic diseases or atherosclerosis.

Applicant's amendment, filed 4/5/04, appears to rely upon amending the claims.

However, as pointed out previously, applicant's amendment, filed 11/12/02, directed written support to pages 15-17, Figures 2A-2B and Example 2 and original claim 18 for the recitation of claim 18(a) and (b).

Pages 15-17, Figures 2A-2B and Example 2 and original claim 18 of the instant application provide for CDR sequences and framework regions for the particular humanized AjvW-2 von Willebrand factor-specific antibody.

The recitation of claim 18(a) and (b) now represents a departure from the specification and claims as originally filed. Applicant's reliance on the disclosure of the humanized AjvW-2 antibodies does not provide sufficient direction and guidance to the "features" currently claimed. The current claims broaden the instant disclosure to any humanized immunoglobulin comprising the certain AJvW2-derived CDR sequences and I3R framework regions. The claims do not recite "AJvW2" as the source material of the claimed humanized antibodies. The claims do not recite the von Willebrand factor specificity.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.
See MPEP 714.02 and 2163.06

6. Claims 18, 21 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating patients having or at risk of a thrombotic disease or atherosclerosis with humanized immunoglobulin comprising the claimed sequences that are "specific for von Willebrand factor", does not reasonably provide enablement for any "humanized immunoglobulin comprising the claimed sequences". The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has not provided sufficient guidance and direction to reliance on accomplishing the claimed therapeutic methods with humanized antibodies comprising the claimed sequences other than humanized antibodies that are "specific for von Willebrand factor". Although the claimed CDR sequences are derived from the particular humanized AjvW von Willebrand factor-specific antibody, the claims do not recite the von Willebrand factor specificity. Immunoglobulins are highly polymorphic. In the absence of defining the von Willebrand specificity, antibodies comprising the claimed CDR sequences do not necessarily have the appropriate specificity in order to accomplish the claimed methods.

Applicant has provided enablement for antibodies that bind von Willebrand factor. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable any "humanized immunoglobulin comprising the claimed sequences.

Applicant should amend the claims to recite the von Willebrand factor specificity to obviate this rejection.

Applicant's arguments, filed 4/5/04, have been fully considered but are not found convincing essentially for the reason of record.

Applicant argues that determining what sequences fall within or outside (versus "without") the scope of the present claims would be readily apparent to the skilled artisan. Accordingly, applicant submit that the present claims are fully enabled by the specification and the common knowledge available in the art.

However, the claims still do not recite that the claimed methods rely upon humanized immunoglobulins are "specific for von Willebrand factor".

Therefore, applicant's arguments in conjunction with the amended claims are not found persuasive.

7. Applicant's amended claims, filed 4/5/04 sand 6/8/04 have obviated the previous rejection as it applies to the instant claims under 35 U.S.C. 112, first paragraph, enablement with respect to the biological material "I3R antibody".

8. Applicant's amended claims, filed 4/5/04 sand 6/8/04 have obviated the previous rejection as it applies to the instant claims under 35 U.S.C. § 112, second paragraph,

9. The following obviousness-type double patenting rejections are maintained for the reasons of record.

Claims 18, 21 and 23-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,613,328 (Co et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant claims, as being drawn to the same or nearly the same methods of treating thrombotic disorders or atherosclerosis with the same or nearly the same the von Willebrand factor-specific humanized AjvW antibodies. Further, the instant limitations, including the sequences set forth in instant claim 18(a) and (b) are derived from the von Willebrand factor-specific humanized AjvW antibody disclosed and claimed in U.S. Patent No. 6,613,328.

Claims 18, 21 and 23-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20 of copending application Serial No. 10/289,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same methods of treating thrombotic disorders or atherosclerosis with the same or nearly the same methods of treating thrombotic disorders or atherosclerosis with the same or nearly the same the von Willebrand factor-specific humanized AjvW antibodies. Further, the instant limitations, including the sequences set forth in instant claim 18(a) and (b) are derived from the von Willebrand factor-specific humanized AjvW antibody disclosed and claimed in copending USSN 10/289,181.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment filed 4/5/04, requests that the obvious double-patenting rejections be held in abeyance until such time allowable subject matter has been identified in the present application.

10. No claim allowed.

As indicated previously, given the claims and prosecution of U.S. Patent No. 6,613,328 (Co et al.), it appears that the instant claims which rely upon the limitations, drawn to sequences set forth in instant claim 18(a) and (b) are derived from the von Willebrand factor-specific humanized AjvW antibody disclosed and claimed in U.S. Patent No. 6,613,328. Accordingly, the claims appear to be free of the prior art.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
August 23, 2004